

REMARKS

5 To further advance the prosecution of the instant application in view of the Office Action and to place the Claims in better form for allowance the applicants submit the above amendments.

 The applicants respectfully request further examination and reconsideration in view of the above amendment and the remarks set forth below.

10 Prior to this amendment, Claims 1-40 were previously pending in this application. By the above amendment, Claims 15-16 and 25-40, which were previously withdrawn, have been canceled. Also by the above amendment, new Claims 41-49 have been added and Claims 1-4, 11 and 17 have been amended. Claims 1-14, 17-24 and new 41-49 are now pending in this application.

15 **Objections:**

 Within the Office Action, the amendment filed October 10, 2000 has been objected to under 35 U.S.C. 132 as introducing new subject matter. Specifically, the objection is based on the grounds that the concept of using or producing a single wavelength is not supported by the original disclosure. Within the Office Action it is stated that the Applicant is required to cancel the new matter.

20 The Applicant respectfully disagrees that the concept of a single wavelength is new subject matter not supported in the original disclosure. Referring to page 7, lines 10-15, it is stated within the present application that “the laser source 31 preferably includes two erbium
25 lasers 32 and 34 which generate the laser beams 33 and 35, respectively” and that “the two laser beams 33 and 35 are combined into a single laser output 37 by the galvanometer 36 which switches between the two laser outputs 33 and 35.” Lasers are inherently mono-chromatic light sources that emit light with a gaussian distribution of a single wavelength. Therefore, a combined single laser output from two laser sources that are the same type of laser will produce a
30 single wavelength laser output. However, in order to further the prosecution of the instant application, the Applicant has removed the recitation of single laser wavelength output from the Claims.

Rejections Under 35 U.S.C. § 112

Claims 1-4 and 16-24 have been rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the Office Action it is specifically stated that the originally filed disclosure is silent on the use of a single wavelength. For the reasons stated above, the applicant traverses the rejection of claims 1-4 and 16-24 under 35 U.S.C. 112 on the grounds that the specification is silent with respect to the use of a single wavelength. However, in order to further the prosecution of the present application, the recitation to a single laser wavelength output has been removed from the Claims 1-4 and 16-24.

Rejections Under 35 U.S.C. § 103

Within the Office Action, Claims 1-3, 6-8, 11-14 and 17-19 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,426 to Sklar et al. (hereinafter "Sklar") in combination with U.S. Patent No. 4,672,969 to Dew (hereinafter "Dew"), U.S. Patent No. 5,620,435 to Belkin et al. (hereinafter "Belkin") and the article entitled "Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation" by R. Rox Anderson and John A. Parrish (hereinafter "Anderson").

The teachings of Sklar are applied as the primary reference in a U.S.C. 103(a) rejection of Claims 1-3, 6-8, 11-14, and 17-19 in the instant application. The teachings of Sklar have been fully characterized in previous communications. Briefly, the teachings of Sklar are directed to a system and method for accurately controlling and positioning laser sources, specifically during surgery. According to Sklar "a limiting factor to the duration of the operation under these procedures (viz. Prior Art procedures) is the surgeon's reaction time while focusing on the target and the patients movement while the surgeon is trying to find the target and react to the target recognition by firing the laser. [Sklar, column 5, lines 13-19] In view of these prior art limitations, Sklar teaches a system for performing precision laser surgery which includes an imaging system for providing a surgeon with precision tracking and topographical information regarding the surgical target area. [Sklar, Abstract] Sklar states that "it is well appreciated that the limitations on the achievable accuracy and control of laser surgical instruments today is no longer paced by the development of laser technology, but by the imaging and tracking technologies needed to efficiently use the laser. [Sklar, column 2, lines 39-43]

Sklar does not teach a laser device, or a laser system, with a laser source having two or more lasers that produce laser beams and which are alternated and combined to generate a single laser output for producing coagulation laser pulses as currently recited in each of the Independent Claims 1, 11 and 17. Nor does Sklar teach a laser device, or a laser system, for generating both
5 ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Sklar does not teach an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49.

Dew teaches a laser healing method to effect wound closure and reconstruction of
10 biological tissue. Optical energy is applied to produce thermal heating of biological tissue to a degree suitable for denaturing the tissue proteins such that the collagenous elements of the tissue form a biological glue to seal and reconstruct the tissue being heated. [Dew, Abstract] The system of Dew includes a laser 20. Dew teaches a marker laser 30 which is coaligned with the infrared beam of the laser 20. Dew teaches that an auxiliary source of optical energy 50 can be
15 incorporated into the apparatus to emit radiation having a wavelength which is intensely absorbed by biological tissue.

Dew does not teach a laser source with two or more lasers that produce laser beams that are alternated and combined to generate a single laser output for generating coagulation laser pulses as currently recited in each of the Independent Claims 1, 11 and 17 or for generating both
20 ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Dew does not teach an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Dew teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

25 Belkin teaches a method for welding ocular tissues to each other using a carbon dioxide laser. [Belkin, col. 2, lines 35-44] Belkin does not teach a medical laser with a laser source with two or more lasers for generating a plurality of coagulative laser pulses.

Belkin does not teach a laser or a laser system with a laser source having two or more lasers that produce laser beams that are alternated and combined to generate a single laser output
30 for generating coagulation laser pulses as currently recited in each of the independent Claims 1, 11 and 17 or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Belkin does not teach an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser

output, as recited in claims 5, 14 and 49. Nor does Belkin teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

Anderson teaches a scheme for confining thermally mediated radiation damage to chosen pigmented targets. [Anderson, p. 524] The technique relies on selective absorption of a brief radiation pulse to generate and confine heat at certain pigmented targets. [Anderson, p. 524] Anderson does not teach a medical laser with a laser system as currently claimed. Specifically, Anderson does not teach laser source with two or more lasers that produce laser beams which are alternated and combined to generate a single laser output for generating coagulation laser pulses as currently recited in each of the Independent Claims 1, 11 and 17, or for generating both ablation and coagulation laser pulses as recited in Independent Claim 41. Further, Anderson does not teach an arm structure for guiding the single laser output, as recited in Claims 3, 14 and 49, or a plurality of refocussing lenses for focussing the single laser output, as recited in claims 5, 14 and 49. Nor does Dew teach a user interface, the elements of which are recited in claims 7, 12, and 44-46.

The current invention is a laser system that utilizes multiple lasers which produce multiple laser beams. The multiple laser beams are alternated with a galvanometer or other suitable device to produce a single laser output which generates coagulation laser pulses. The laser system preferably also is configured to generate ablation laser pulses. The single laser output is preferably guided to a target tissue through an articulated arm with a series of refocussing optics. The system preferably has a user interface that allows a user to select laser pulse patterns, target sizes and operating modes. The interface preferably is a graphical user interface that displays the selected laser pulse pattern and allows the user to select a desired ablation depth value and coagulation depth value. The combinations of features claimed in the instant application are neither taught or suggested by Sklar, Dew, Belkin, Anderson nor their combination.

The independent Claim 1 is directed to a medical laser delivery apparatus for delivering one or more pulses to an area of tissue to be treated and generating a region of coagulation to a controllable coagulation depth under a surface of the area of tissue. The system has a laser source for generating a series of one or more non-ablative laser pulses to be delivered to the area of tissue to be treated in order to raise a temperature at the surface of the area of tissue to be treated to a temperature sufficient to generate coagulation at the coagulation depth when the laser source is in a coagulation mode, wherein the laser source comprises two or more lasers for generating two or more corresponding laser beams which are alternated to produce a single laser

output which provides the series of one or more non-ablative laser pulses. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are alternated to produce a single laser output which provides the series of one or more non-ablative laser pulses. For at least these reasons, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 2, 3 and 6-8 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 2, 3 and 6-8 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 11 is directed to medical laser having a laser source having two or more lasers which are combined in an alternating fashion for generating a laser output having a predetermined absorption, wherein the predetermined absorption forms a predetermined coagulation depth. The medical laser of Claim 11 also has a laser control system coupled to the laser source for controlling the laser source to generate a plurality of coagulative laser pulses from the laser output, such that each such coagulative laser pulse is delivered in sequence to a target area. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser with a laser source with two or more lasers which are combined in an alternating fashion for generating a laser output to generate a plurality of coagulative laser pulses. For at least these reasons, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 12-14 are all dependent on the independent Claim 11. As described above, the independent Claim 11 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 12-14 are all also allowable as being dependent upon an allowable base claim.

The independent Claim 17 is directed to a medical laser delivery apparatus for treating an area of tissue. The medical laser delivery apparatus has a laser source having two or more lasers which are combined in an alternating fashion into a single laser output by a combining apparatus for generating a series of one or more laser pulses each having a strength and a duration. The apparatus also has a laser delivery system coupled to the laser source for delivering the laser pulses from the laser source to the area of tissue being treated and a control system coupled to the laser source for controlling generation of the laser pulses from the laser source, wherein the laser source operates in both an ablation mode and a coagulation mode such that when in the ablation

mode, the strength and duration of the laser pulses are sufficient to ablate tissue at the area of tissue being treated to a controllable ablation depth and when in the coagulation mode, the strength and duration of the laser pulses are sufficient to generate a coagulation region having a controllable coagulation depth within the tissue remaining at the area of tissue being treated without ablating any tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser delivery apparatus which has two or more lasers which are combined in an alternating fashion into a single laser output and a control system coupled for controlling the laser source for generating laser pulses with the strength and duration for both ablation and coagulation. For at least these reasons, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 18 and 19 are both dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 18 and 19 are both allowable as being dependent upon an allowable base claim.

The new independent Claim 41 is directed to a dual mode medical laser system, for sequentially ablating and coagulating a region of target tissue with ablation laser pluses followed by coagulation laser pulses to the region of target tissues. The dual mode medical laser system has a laser source comprising a first laser and a second laser for generating a first laser beam and a second laser beam at a same wavelength and a means to alternate between the first laser beam and the second laser beam to provide a single laser output to provide the ablation laser pulses and the coagulation laser pulses. The medical laser system also has a means to direct the single laser output to the region of the target tissue. As discussed above, neither Sklar, Dew, Belkin, Anderson nor their combination teach a medical laser delivery apparatus having a first and second laser that produce laser beams that are alternated to produce ablation and coagulation laser pulses from a single laser output. For at least these reasons, the new independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination.

Claims 42-49 all dependent on the independent Claim 41. As described above, the independent Claim 41 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 42-49 are all allowable as being dependent upon an allowable base claim.

Within the Office Action, Claims 4, 5, 9, 10 and 20-24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Sklar in combination with Dew, Anderson, Belkin and further in view of U.S. Patent No. 5,938,657 to Assa et al. (hereinafter "Assa"). Assa teaches an apparatus for delivering energy with a continuous output.

5 Claims 4, 5, 9 and 10 are all dependent on the independent Claim 1. As described above, the independent Claim 1 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 4, 5, 9 and 10 are all also allowable as being dependent upon an allowable base claim.

10 Claims 20-24 are all dependent on the independent Claim 17. As described above, the independent Claim 17 is allowable over the teachings of Sklar, Dew, Belkin, Anderson and their combination. Accordingly, Claims 20-24 are all also allowable as being dependent upon an allowable base claim.

15 For the reasons given above, Applicants respectfully submit that the claims are in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (650) 833-0160 to discuss the same so that any outstanding issues can be expeditiously resolved.

20 Respectfully submitted,
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Version of Amended Claims with Markings to Show Changes Made:

Please cancel Claims 15-16 and Claims 25-40.

- 1 1. (Thrice Amended) A medical laser delivery apparatus for delivering one or more pulses
2 to an area of tissue to be treated and generating a region of coagulation to a controllable
3 coagulation depth under a surface of the area of tissue comprising a laser source for
4 generating a series of one or more non-ablative laser pulses to be delivered to the area of
5 tissue to be treated in order to raise a temperature at the surface of the area of tissue to be
6 treated to a temperature sufficient to generate coagulation at the coagulation depth when
7 the laser source is in a coagulation mode, wherein the laser source comprises two or more
8 lasers for generating two or more corresponding laser beams which are [combined into]
9 alternated to produce a single laser [wavelength] output [to provide] which provides the
10 series of one or more non-ablative laser pulses.
- 1 2. (Amended) The medical laser delivery apparatus as claimed in claim 1 wherein the single
2 laser output is focussed to the target tissue through an arm feature [further comprising a
3 laser delivery system coupled to the laser source for delivering the one or more pulses
4 from the laser source to the area of tissue to be treated].
- 1 3. (Amended) The medical laser delivery apparatus as claimed in claim 2 wherein the [laser
2 delivery system comprises] arm feature is an articulated arm and one or more refocussing
3 optics for refocussing the laser pulses as they travel through the articulated arm.
- 1 4. (Amended) The medical laser delivery apparatus as claimed in claim 3 wherein the laser
2 delivery system further comprises a scanning handpiece at an end of the arm feature for
3 [providing] guiding the series of one or more non-ablative laser pulses to the area of
4 tissue being treated.
- 1 11. (Thrice Amended) A medical laser comprising:
2 a. a laser source having two or more lasers which are combined in an alternating
3 fashion for generating a laser [beam] output having a predetermined absorption
4 [wavelength], wherein the predetermined absorption [wavelength] forms a
5 predetermined coagulation depth [in response to an ablative laser pulse]; and

- 6 b. a laser control system coupled to the laser source for controlling the laser source
7 [for generating] to generate a plurality of coagulative laser pulses from the laser
8 output, such that each such coagulative laser pulse is delivered in sequence to a
9 target area [to form a coagulation region deeper than the predetermined
10 coagulation depth].

1 17. (Thrice Amended) A medical laser delivery apparatus for treating an area of tissue
2 comprising:

- 3 a. a laser source having two or more lasers which are combined in an alternating
4 fashion into a single laser [wavelength] output by a combining apparatus for
5 generating a series of one or more laser pulses each having a strength and a
6 duration;
7 b. a laser delivery system coupled to the laser source for delivering the laser pulses
8 from the laser source to the area of tissue being treated;
9 c. a control system coupled to the laser source for controlling generation of the laser
10 pulses from the laser source, wherein the laser source operates in both an ablation
11 mode and a coagulation mode such that when in the ablation mode, the strength
12 and duration of the laser pulses are sufficient to ablate tissue at the area of tissue
13 being treated to a controllable ablation depth and when in the coagulation mode,
14 the strength and duration of the laser pulses are sufficient to generate a
15 coagulation region having a controllable coagulation depth within the tissue
16 remaining at the area of tissue being treated without ablating any tissue.

1 41. (New) A dual mode medical laser system, for sequentially ablating and coagulating a
2 region of target tissue with ablation laser pulses followed by coagulation laser pulses to
3 the region of target tissue, the dual mode medical laser system comprising:

- 4 a. a laser source comprising a first laser and a second laser for generating a first laser
5 beam and a second laser beam at a same wavelength;
6 b. means to alternate between the first laser beam and the second laser beam to
7 provide a single laser output to provide the ablation laser pulses and the
8 coagulation laser pulses; and
9 c. means to direct the single laser output to the region of the target tissue.

- 1 42. (New) The dual mode medical laser system of claims 41 wherein the first laser and the
2 second laser are Er:YAG lasers.
- 1 43. (New) The dual mode medical laser system of claim 41 wherein the means to alternate
2 between the first laser beam and the second laser beam is a galvanometer.
- 1 44. (New) The dual mode medical laser system of claim 41 further comprising a user
2 interface, wherein a user selects an ablation depth and a coagulation depth and wherein a
3 series of the ablation laser pluses with a fluence corresponding to the selected ablation
4 depth are generated followed by a series of the coagulation laser pulses with a fluence
5 corresponding to the selected coagulation depth.
- 1 45. (New) The dual mode medical laser system of claim 44 wherein the user interface
2 comprises a mode selector for selecting between manual mode and scan mode, wherein
3 the user further selects a scan size and a laser pulse pattern with the scan mode selected.
- 1 46. (New) The dual mode medical laser system of claim 45 wherein the user interface is a
2 graphical user interface for displaying the selected laser pulse pattern.
- 1 47. (New) The dual mode medical laser system of claim 41 wherein the ablation laser pulses
2 have a duration of approximately 500 microseconds and a fluence of approximately 2
3 Joules/cm².
- 1 48. (New) The dual mode medical laser system of claim 41 wherein the coagulation laser
2 pulses have a duration of approximately 150 microseconds and a fluence of
3 approximately 200 millijoules/cm².
- 1 49. (New) The dual mode medical laser system of claim 41 wherein the means to direct the
2 single laser output to the region of the target tissue comprises an articulated arm feature
3 with a plurality of refocussing lenses for guiding and focussing the single laser output
4 through the articulated arm feature.